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9

10 **UNITED STATES DISTRICT COURT**
11 **DISTRICT OF NEVADA**

12

13 UNITED STATES OF AMERICA,

14 Plaintiff,

15 v.

16 AFFINITYLIFESTYLES.COM, INC., and
17 REAL WATER, INC., corporations, and
BRENT A. JONES and BLAIN K. JONES,
18 individuals,

19 Defendants.

20 Case No. 21-cv-959-JAD-BNW

21

22 **CONSENT DECREE OF PERMANENT**
INJUNCTION

23 ECF No. 3

24 Plaintiff, the United States of America, on behalf of the United States Food and Drug
25 Administration (“FDA”), by its undersigned attorneys, having filed a Complaint for Injunction
26 (“Complaint”) against Affinitylifestyles.com, Inc., and Real Water, Inc., corporations; and Brent
A. Jones and Blain K. Jones, individuals (collectively, “Defendants”), and Defendants having
appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the
“Decree”) without contest and without admitting the violations described herein, and before any
testimony has been taken, and the United States of America having consented to this Decree:

27

28 **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** as follows:

1 1. This Court has jurisdiction over the subject matter and all parties to this action.

2 2. The Complaint states a cause of action against Defendants under the Federal Food,
3 Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the “Act”).

4 3. Defendants violated 21 U.S.C. § 331(uu), by operating a facility that manufactured,
5 processed, packed, or held food for sale in the United States, and not doing so in compliance
6 with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g.

7 4. Defendants violated 21 U.S.C. § 331(a), by introducing or delivering for introduction
8 into interstate commerce, or causing to be introduced or delivered for introduction into interstate
9 commerce, articles of food that were adulterated within the meaning of 21 U.S.C. § 342(a)(4) in
10 that they have been prepared, packed, or held under insanitary conditions whereby they may
11 have become contaminated with filth, or whereby they may have been rendered injurious to
12 health.

13 5. Defendants violated 21 U.S.C. § 331(k), by causing articles of food that were held for
14 sale after shipment of one or more of their components in interstate commerce to become
15 adulterated under 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under
16 insanitary conditions whereby they may have become contaminated with filth, or whereby they
17 may have been rendered injurious to health.

18 6. Defendants violated 21 U.S.C. § 331(a), by introducing or delivering for introduction
19 into interstate commerce, or causing to be introduced or delivered for introduction into interstate
20 commerce, articles of food that were misbranded within the meaning of 21 U.S.C. § 343(i)(2).

21 7. Defendants violated 21 U.S.C. § 331(k), by causing articles of food that were held for
22 sale after shipment of one or more of their components in interstate commerce to become
23 misbranded within the meaning of 21 U.S.C. § 343(i)(2).

24 8. For the purposes of this Decree, the following definitions shall apply:

25 A. “Defendants’ Facilities” mean the facilities located at 1180 Center Point Drive,
26 Suite 200, Henderson, Nevada, and 6018 E. Main Street, Mesa, Arizona, and/or any other
27 location(s) at which Defendants now or in the future directly or indirectly manufacture, process,
28 prepare, bottle, pack, label, hold, and/or distribute any article of food; and

1 B. “Defendants’ Products” shall refer to Defendants’ “Re2al Water Drinking Water”
2 and “Re2al Alkalized Water” bottled drinking water (together, “Re2al Water”) and “Re2al
3 Alkalized Water Concentrate” chemical concentrate (“E2 Concentrate”), as well as any other
4 article of food that Defendants now or in the future directly or indirectly manufacture, process,
5 prepare, bottle, pack, label, hold, and/or distribute; and

6 C. “CGMP” shall refer to current good manufacturing practice requirements for
7 human food (set forth at 21 C.F.R. Part 117, Subpart B) and bottled drinking water (set forth at
8 21 C.F.R. Part 129).

9 9. Upon entry of this Decree, Defendants and each and all of their directors, officers,
10 agents, representatives, employees, attorneys, successors and assigns, and any and all persons in
11 active concert or participation with any of them (including individuals, partnerships,
12 corporations, subsidiaries, affiliates, and “doing business as” entities) (collectively, “Associated
13 Persons”) who have received actual notice of this Decree by personal service or otherwise, are
14 permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable
15 authority of this Court, from directly or indirectly manufacturing, processing, preparing, bottling,
16 packing, labeling, holding, and/or distributing articles of food at or from Defendants’ Facilities
17 unless and until:

18 A. Defendants retain, at Defendants’ expense, an independent person or persons (the
19 “Food Safety & Preventive Controls (‘PC’) Expert”) who is without any personal or financial
20 ties (other than the retention agreement) to Defendants or their families, who meets the
21 requirements of a preventive controls qualified individual (“PCQI”) as defined in 21 C.F.R. §
22 117.3, and who, by reason of background, training, education, and experience, is qualified: (1) to
23 establish methods, processes, and controls at Defendants’ Facilities to ensure that articles of food
24 are manufactured, processed, prepared, bottled, packed, labeled, held, and distributed in
25 compliance with CGMP; (2) to develop and implement a written Sanitation Plan, a Bottling Plan,
26 and a Food Safety Plan in accordance with 9(B) below; and (3) to inspect Defendants’ Facilities
27 to determine whether Defendants’ methods, processes, and controls are continuously operated
28 and administered in conformity with this Decree, the Act, and its implementing regulations.

1 Defendants shall notify FDA in writing of the identity and qualifications of the Food Safety &
2 PC Expert within two (2) business days after retaining such Food Safety & PC Expert; and

3 B. The Food Safety & PC Expert, in conjunction with Defendants:

4 (1) Review all FDA inspectional observations of deficiencies at Defendants'
5 Facilities from March/April 2021 to the present and develop, to FDA's satisfaction:

6 a. A written Sanitation Plan and Sanitation Standard Operating Procedures
7 (hereafter, "Sanitation Plan") for manufacturing, processing, preparing, packing, holding, and
8 distributing articles of food. Such Sanitation Plan shall ensure that Defendants' manufacturing
9 processes, cleaning and sanitizing operations, monitoring, and corrective actions, protect against
10 the contamination of food and food-contact surfaces and prevent insanitary conditions at
11 Defendants' Facilities, and shall address, but not be limited to, contamination by chemical
12 hazards and environmental pathogens; and

13 b. A written Bottled Water Processing & Bottling Plan (hereafter, "Bottling
14 Plan") for processing, bottling, and holding of bottled drinking water. Such Bottling Plan shall
15 ensure that Defendants' manufacturing and bottling processes, cleaning and sanitizing
16 operations, sampling and sampling analysis, monitoring, and corrective actions, comply with
17 applicable standards, protect against the contamination of bottled drinking water and water-
18 contact surfaces, and prevent insanitary conditions at Defendants' Facilities, and shall address,
19 but not be limited to, contamination by chemical hazards and environmental pathogens; and

20 (2) Ensure that Defendants adhere to the Act, the Current Good Manufacturing
21 Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule ("Food
22 CGMP & PC Rule"), 21 C.F.R. Part 117, and the Processing and Bottling of Bottled Drinking
23 Water Rule ("Bottled Water CGMP Rule"), 21 C.F.R. Part 129; and

24 (3) Conduct a hazard analysis of all foods manufactured by Defendants and
25 develop, to FDA's satisfaction, a written Food Safety Plan identifying required preventive
26 controls for Defendants' Products and manufacturing processes consistent with the Food CGMP
27 & PC Rule and the Bottled Water CGMP Rule, and establishing adequate measures to control for
28 all hazards requiring preventive controls consistent with 21 C.F.R. Part 117 Subpart C and

1 associated subparts; and

2 (4) Develop, to FDA's satisfaction, a written employee training program (in English
3 and any other language necessary to convey the substance of the training), addressing the Food
4 CGMP & PC Rule, the Bottled Water CGMP Rule, the Sanitation Plan, the Bottling Plan, and
5 the Food Safety Plan approved by FDA under paragraph 9(C), and after receiving FDA's
6 approval of such program in accordance with paragraph 9(C), train Defendants and their officers,
7 employees, and all other persons who perform duties at Defendants' Facilities in accordance with
8 such program, which shall include, but not be limited to, maintaining sanitation, conducting
9 adequate sampling and analysis, avoiding microbial contamination, and controlling chemical
10 hazards and environmental pathogens; and (5) Submit to FDA documentation demonstrating that
11 the Food Safety & PC Expert has adequately trained Defendants and their officers, employees,
12 and all other persons who perform duties at Defendants' Facilities; and

13 C. FDA has approved, in writing, the Sanitation Plan, Bottling Plan, Food Safety
14 Plan, and employee training program developed by the Expert, as specified in paragraph 9(B);
15 and

16 D. Defendants:

17 (1) Assign continuing responsibility for implementing and monitoring the
18 Sanitation Plan and the Bottling Plan to a person(s) who is trained in processing and bottled
19 drinking water requirements, see 21 C.F.R. Part 129, and who, by reason of background,
20 education, training, or experience, is qualified to maintain Defendants' Facilities in a sanitary
21 condition, coordinate and implement any necessary corrective actions, and who meets the
22 requirements of a PCQI as defined in 21 C.F.R. §117.3, and Defendants provide such person
23 with the authority and resources to achieve any necessary corrective action; and

24 (2) Ensure that the FDA-approved Sanitation Plan, Bottling Plan and Food Safety
25 Plan are available and accessible (in English and any other language necessary to convey the
26 substance of such documents) to their officers, employees, and all other persons who perform
27 duties at Defendants' Facilities; and

28 (3) Successfully complete the FDA-approved employee training program; and

(4) Destroy, under FDA's supervision, and in accordance with the procedures in paragraph 11, all articles of food and food ingredients (including but not limited to in-process and finished articles of food), as well as all unused labels and empty labeled bottles, in Defendants' custody, control, or possession as of the date this Decree is signed by the parties; and

(5) At their expense, clean and sanitize Defendants' Facilities and equipment therein to render Defendants' Facilities and equipment suitable for manufacturing, processing, preparing, bottling, packing, labeling, holding, and distributing articles of food in accordance with this Decree, the Act, and its implementing regulations, and ensure that Defendants' Facilities and equipment therein will be continuously maintained in a sanitary condition; and

E. The Food Safety & PC Expert conducts a comprehensive inspection of Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, bottle, pack, label, hold, and/or distribute articles of food and certifies in writing to FDA that: (1) he or she has inspected Defendants' Facilities, and the methods, processes, and controls used to manufacture, process, prepare, bottle, pack, label, hold, and distribute articles of food; (2) Defendants have corrected all the deficiencies observed by FDA during FDA's March/April 2021 inspections, specifying each FDA inspectional observation and Defendants' corrections thereof; and (3) Defendants' Facilities and the methods, processes, and controls used to manufacture, process, prepare, bottle, pack, label, hold, and distribute articles of food are, in the Food Safety & PC Expert's opinion, in compliance with this Decree (including the written Sanitation Plan, Bottling Plan, and Food Safety Plan), the Act, and its implementing regulations, including but not limited to the Food CGMP & PC Rule and the Bottled Water CGMP Rule. Defendants shall ensure that the Food Safety & PC Expert's written certification contains a detailed report of the Food Safety & PC Expert's inspectional findings and includes, but is not limited to, a determination that Defendants have implemented procedures that are adequate to ensure continuing compliance with the Sanitation Plan, Bottling Plan, Food Safety Plan, the Food CGMP & PC Rule, and the Bottled Water CGMP Rule. Defendants shall also ensure that the Food CGMP & PC Expert's written certification with supporting documentation is submitted

1 to Defendants and FDA concurrently, within ten (10) business days after completing the
2 inspection; and

3 F. Defendants retain, at Defendants' expense, an independent person (the "Labeling
4 Expert") who is without any personal or financial ties (other than a retention agreement) to
5 Defendants or their families, except that this person may be the same as the Food Safety & PC
6 Expert, and who, by reason of background, training, education, or experience, is qualified to
7 review Defendants' product labeling to determine whether it complies with 21 U.S.C. § 343 and
8 all applicable regulations. Defendants shall notify FDA in writing of the identity and
9 qualifications of the Labeling Expert within three (3) business days after retaining such Labeling
10 Expert; and

11 G. The Labeling Expert performs a comprehensive review of Defendants' product
12 labeling and certifies in writing to FDA that: (1) he or she has reviewed Defendants' product
13 labeling; (2) all deviations from 21 U.S.C. § 343 and applicable regulations that have been
14 brought to Defendants' attention by FDA, the Labeling Expert, and any other source, have been
15 corrected; and (3) Defendants' product labeling is, in the Labeling Expert's opinion, in
16 compliance with this Decree, the Act, and its implementing regulations. Defendants shall ensure
17 that the Labeling Expert's written certification contains a detailed report of the Labeling Expert's
18 review that includes, but is not limited to, samples of all reviewed product labels and a
19 determination that Defendants have implemented procedures that are adequate to ensure that
20 their labeling complies with 21 U.S.C. § 343 and all applicable regulations. Defendants shall also
21 ensure that the Labeling Expert's written certification with supporting documentation is
22 submitted to Defendants and FDA concurrently, within ten (10) business days after completing
23 the labeling review; and

24 H. Defendants recall and destroy, under FDA's supervision and in accordance with
25 the procedures provided in paragraphs 10-11, all of Defendants' Re2al Water and E2
26 Concentrate that were manufactured, processed, prepared, bottled, packed, labeled, held, and/or
27 distributed by Defendants through and including the date of entry of this Decree; and

28 I. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of

1 this Decree, the Act, and its implementing regulations, including but not limited to the Food
2 CGMP & PC Rule and the Bottled Water CGMP Rule, inspects Defendants' Facilities, including
3 the buildings, sanitation-related systems, equipment, utensils, and all articles of food and relevant
4 records contained therein; and

5 J. FDA notifies Defendants in writing that Defendants appear to be in compliance
6 with the requirements set forth in paragraphs 9(A) – 9(H) of this Decree, the Act, and its
7 implementing regulations. In no circumstance shall FDA's silence be construed as a substitute
8 for written notification.

9 10. Within three (3) business days after entry of this Decree, Defendants shall submit to
11 FDA for review and written concurrence a plan to recall Defendants' Products identified in
12 paragraph 9(H). The recall plan shall include customer notifications, public warning, methods for
13 conducting effectiveness checks, and plans for product disposition. Within five (5) business days
14 after receiving FDA concurrence on the recall plan, Defendants shall initiate a recall pursuant to
the recall plan.

15 11. Within fifteen (15) business days after completing the recall of all Defendants'
16 Products identified in paragraph 9(H), Defendants shall give notice to FDA that, under FDA's
17 supervision, Defendants are prepared to destroy all Defendants' Products identified in paragraph
18 9(H) in Defendants' possession, custody, or control. Defendants' notice shall specify the
19 proposed time, place, and method of destruction. Defendants shall not commence or permit any
20 other person to commence destruction until they have received written authorization from FDA
21 to commence the destruction. Within fifteen (15) business days after receiving authorization
22 from FDA to commence destruction, Defendants shall, under FDA supervision, complete the
23 destruction in compliance with this Decree. Defendants shall not dispose of any such products in
24 a manner contrary to the provisions of the Act, any other federal law, any court order, or the laws
25 of any state or Territory, as defined in the Act, in which the products are disposed. Defendants
26 shall bear all costs of destruction and FDA's supervision.

27 12. Upon resuming operations after complying with paragraph 9 and receiving FDA's
28 written notification pursuant to paragraph 9(J), Defendants shall meet the following

1 requirements:

2 A. Defendants shall continuously and effectively implement, on an ongoing basis, the
3 Sanitation Plan, Bottling Plan, and the Food Safety Plan, and employee training program
4 developed pursuant to paragraph 9(B) and approved by FDA pursuant to paragraph 9(C), which
5 training program shall be completed by each new employee within five (5) business days after
6 the new employee commences duties at Defendants' Facilities, and shall include ongoing
7 training programs for employees; and

8 B. Defendants shall retain an independent person or persons (the "Auditor") who
9 shall meet the criteria for and may be the same person as the Food Safety & PC Expert and
10 Labeling Expert(s) described in paragraphs 9(A) and 9(F), to conduct audit inspections of
11 Defendants' Facilities and the methods, processes, and controls used to manufacture, process,
12 prepare, bottle, pack, label, hold, or distribute articles of food, and of Defendants' product
13 labeling, as follows:

14 (1) Within thirty (30) business days after Defendants resume their operations after
15 completing the requirements in paragraph 9, the Auditor shall conduct an audit of Defendants'
16 Facilities and the methods and controls used to manufacture, process, prepare, bottle, pack, label,
17 hold, and distribute articles of food to determine whether Defendants are operating in compliance
18 with this Decree, the Act, and its implementing regulations, and to identify any deviations from
19 such requirements. The Auditor shall submit an Audit Report documenting all findings to
20 Defendants and FDA concurrently, within seven (7) business days after completing the audit;
21 and

22 (2) Thereafter, the Auditor shall conduct audits no less frequently than once every
23 (3) months for a period of no less than one (1) year, and then at least once every six (6) months
24 for the next two (2) years. Beginning in the fourth year after Defendants resume their operations
25 after completing the requirements of paragraph 9, the Auditor shall conduct audits at least
26 annually unless FDA informs Defendants in writing that more frequent audit inspections and
27 reporting are required. If any Audit Report identifies any deviation from this Decree, the Act, or
28 its implementing regulations, FDA, in its discretion, may require the audit cycle to begin anew;

1 and

2 (3) As part of every Audit Report (except the first one), the Auditor shall assess
3 adequacy of actions taken by Defendants to correct all previous audit observations indicating that
4 Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If
5 the Audit Report contains any audit observations indicating that Defendants are not in
6 compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all
7 necessary corrections within ten (10) business days after receipt of the Audit Report, unless FDA
8 notifies Defendants in writing that a shorter time period is necessary; and

9 (4) Within twenty (20) business days after the required completion date for any
10 corrective action under paragraph 12(B)(3), the Auditor shall review each and all corrective
11 action(s) taken by Defendants and report in writing to FDA whether each deviation listed in the
12 Audit Report has been corrected.

13 13. Upon entry of this Decree, and after Defendants receive notification under paragraph
14 9(J) from FDA that they are permitted to resume operations, Defendants and all Associated
15 Persons, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or
16 indirectly doing or causing to be done any of the following acts:

17 A. Violating 21 U.S.C. § 331(uu), by operating a facility that manufactures,
18 processes, packs, or holds food for sale in the United States, and not doing so in compliance with
19 the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g; and

20 B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into
21 interstate commerce, or causing the introduction or delivery for introduction into interstate
22 commerce, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4)
23 and/or misbranded within the meaning of 21 U.S.C. § 343; and

24 C. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after
25 shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. §
26 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343; and

27 D. Failing to implement and continuously maintain the requirements of the Act, its
28 implementing regulations, and this Decree.

1 14. If, at any time after this entry of this Decree, FDA determines, based on the results of
2 an inspection, the analysis of a sample, report or data prepared or submitted by Defendants, the
3 Food Safety & PC Expert, the Labeling Expert, the Auditor, or any other information, that
4 Defendants have failed to comply with any provision of this Decree, have violated the Act or its
5 implementing regulations, or that additional corrective actions are necessary to achieve
6 compliance with this Decree, the Act, or its applicable regulations, FDA may, as and when it
7 deems necessary, notify Defendants in writing of the noncompliance and order Defendants to
8 take appropriate corrective action, including, but not limited to, ordering Defendants to
9 immediately take one or more of the following actions:

10 A. Cease manufacturing, processing, preparing, bottling, packing, labeling, holding,
11 and/or distributing any and all articles of food;

12 B. Recall, at Defendants' expense, any and all articles of food that have been
13 distributed and/or are under the custody and control of Defendants' agents, distributors,
14 customers, or consumers that in FDA's judgment is adulterated, misbranded, or otherwise in
15 violation of this Decree, the Act, or its implementing regulations;

16 C. Revise, modify, expand, or continue to submit any reports or plans prepared
17 pursuant to this Decree;

18 D. Submit additional reports or information to FDA as requested;

19 E. Submit samples to a qualified laboratory for analysis;

20 F. Institute or reimplement any of the requirements set forth in this Decree;

21 G. Issue a safety alert; and/or

22 H. Take any other corrective actions as FDA, in its discretion, deems necessary to
23 protect the public health or bring Defendants into compliance with this Decree, the Act, or its
24 implementing regulations.

25 This remedy shall be separate and apart from, and in addition to, any other remedy
26 available to the United States under this Decree or under the law.

27 15. Upon receipt of any order issued by FDA pursuant to paragraph 14, Defendants shall
28 immediately and fully comply with the terms of the order. Any cessation of operations or other

1 action described in paragraph 14 shall continue until Defendants receive written notification
2 from FDA that Defendants appear to be in compliance with this Decree, the Act, and its
3 implementing regulations, and that Defendants may resume operations. The cost of FDA
4 inspections, investigations, supervision, examinations, sampling, testing, travel time, and
5 subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be
6 borne by Defendants at the rates specified in paragraph 18.

7 16. Representatives of FDA shall be permitted, without prior notice and as and when
8 FDA deems necessary, to inspect Defendants' Facilities, collect samples, and, without prior
9 notice, take any other measures necessary to monitor and ensure continuing compliance with the
10 terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA
11 representatives shall be permitted: immediate access to Defendants' Facilities and/or other
12 place(s) of business, including but not limited to all buildings or other structures, equipment, raw
13 ingredients, in-process or unfinished and finished materials and products, and containers; to take
14 photographs and make video recordings; to take samples of Defendants' raw ingredients,
15 finished and unfinished materials and products, and containers; and examine and copy all records
16 relating to the receipt, holding, and distribution of any and all of Defendants' Products and their
17 components. The inspections shall be permitted upon presentation of a copy of this Decree and
18 appropriate credentials. The inspection authority granted by this Decree is separate and apart
19 from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

20 17. Defendants shall promptly provide any information or records to FDA upon request
21 regarding the manufacturing, processing, preparing, bottling, packing, labeling, holding, and/or
22 distributing of Defendants' Products. Defendants shall maintain copies of their Sanitation Plan,
23 Bottling Plan, and their Food Safety Plan, along with copies of all records required by such plans
24 and this Decree, at Defendants' Facilities, in a location where the records are readily available
25 for reference and inspection by FDA. Defendants shall retain all records referred to in this
26 paragraph for at least three (3) years after the date the records are prepared.

27 18. Defendants shall pay all costs of FDA's inspections, investigations, supervision,
28 analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants'

1 compliance with any part of this Decree, including all transportation and associated costs for
2 FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred.
3 As of the date of entry of this Decree, these rates are: \$102.39 per hour or fraction thereof per
4 representative for inspection and investigative work; \$122.71 per hour or fraction thereof per
5 representative for analytical or review work; \$0.56 per mile for travel expenses by automobile;
6 government rate or the equivalent for travel by air or other means; and the published government
7 per diem rate for subsistence expenses where necessary. In the event that the standard rates
8 applicable to FDA supervision of court-ordered compliance are modified, these rates shall be
9 increased or decreased without further order of the Court.

10 19. Within five (5) business days after the entry of this Decree, Defendants shall post a
11 copy of this Decree in a common area at Defendants' Facilities and at any other location at
12 which Defendants conduct business and shall ensure that this Decree remains posted for as long
13 as this Decree remains in effect. Within ten (10) business days after entry of this Decree,
14 Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the
15 facts stated therein, stating the fact and manner of compliance with this paragraph.

16 20. Within ten (10) business days after the entry of this Decree, Defendants shall provide
17 a copy of this Decree by personal service or certified mail (return receipt requested) to each and
18 all Associated Persons. Within twenty (20) business days after the date of entry of this Decree,
19 Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance
20 with this paragraph, including identifying the names, addresses, and positions of all Associated
21 Persons who have received a copy of this Decree pursuant to this paragraph.

22 21. In the event that any of the Defendants becomes associated with any additional
23 Associated Person(s) at any time after entry of this Decree, Defendants shall within ten (10)
24 business days after the commencement of such association: (a) provide a copy of this Decree, by
25 personal service or certified mail (return receipt requested), to such Associated Person(s); and (b)
26 provide to FDA an affidavit stating the fact and manner of compliance with this paragraph,
27 identifying the names, addresses, and positions of all Associated Persons who received a copy of
28 this Decree pursuant to this paragraph.

1 22. Defendants shall notify FDA in writing at least fifteen (15) business days before any
2 change in ownership, name, or character of their business that occurs after entry of this Decree,
3 including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution,
4 bankruptcy, assignment, sale, or any other change in the structure or identity of
5 AffinityLifestyles.com, Inc., Real Water, Inc., or the sale or assignment of any business assets,
6 such as Defendants' Facilities, and other buildings or structures, equipment, or inventory that
7 may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree
8 to any prospective successor or assign at least twenty (20) business days prior to any sale or
9 assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph
10 no later than ten (10) business days prior to such assignment or change in ownership.

11 23. All notifications, correspondence, and communications to FDA required by the terms
12 of this Decree shall be prominently marked "Decree Correspondence" and addressed to Program
13 Division Director, Office of Human and Animal Food Operations West 5 (HAFW 5), San
14 Francisco District Office, U.S. Food and Drug Administration, 1201 Harbor Bay Parkway,
15 Alameda, CA 94502, with a copy to ORAHAFWEST5FirmResponses@fda.hhs.gov, and shall
16 reference this civil action by case name and civil action number.

17 24. Should the United States bring and prevail in a contempt action to enforce the terms
18 of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its
19 attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses,
20 investigational and analytical expenses, expert witness fees, administrative and court costs, and
21 any other costs or fees relating to such contempt proceedings.

22 25. Except as provided in the foregoing provisions of this Decree, the parties shall bear
23 their own costs and attorneys' fees in this action.

24 26. Defendants consent to the entry of the Decree, before any testimony has been taken,
25 without contest and without admitting the violations described herein.

26 27. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final.
27 All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if
28 contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in

1 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this
2 Decree shall be based exclusively on the written record before FDA at the time the decision was
3 made. No discovery shall be taken by either party.

4 28. This Court retains jurisdiction over this action and the parties thereto for the purpose
5 of enforcing and modifying this Decree and for the purpose of granting such additional relief as
6 may be necessary or appropriate.

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8 
9 U.S. District Judge Jennifer A. Dorsey
10 Dated: May 31, 2021

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12
13
14
15 The undersigned hereby consent to the entry of the foregoing Decree.
16
17 For Defendants For Plaintiff

18 _____
19 BRENT A. JONES
20 Individually and on behalf of
AFFINITYLIFESTYLES.COM, INC.
and REAL WATER, INC.

21 _____
22 BLAIN K. JONES
23 Individually and on behalf of
AFFINITYLIFESTYLES.COM, INC.
and REAL WATER, INC.

24 _____
25 
J. LEE GRAY
26 Holland & Hart LLP
27 Attorney for Defendants.

28 _____
CHRISTOPHER CHIOU
Acting United States Attorney
District of Nevada

GUSTAV W. EYLER
Director
Consumer Protection Branch

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SARAH WILLIAMS
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P.O. Box 386
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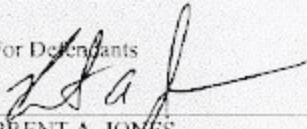
1 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this
2 Decree shall be based exclusively on the written record before FDA at the time the decision was
3 made. No discovery shall be taken by either party.

4 28. This Court retains jurisdiction over this action and the parties thereto for the purpose
5 of enforcing and modifying this Decree and for the purpose of granting such additional relief as
6 may be necessary or appropriate.
7
8

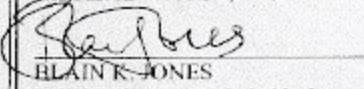
9 **IT IS SO ORDERED**, this _____ day of _____, 2021.
10
11
12

13 **UNITED STATES DISTRICT JUDGE**
14
15

16 The undersigned hereby consent to the entry of the foregoing Decree.
17

18 For Defendants

19 BRENT A. JONES
20 Individually and on behalf of
AFFINITYLIFESTYLES.COM, INC.
and REAL WATER, INC.

21 For Plaintiff
22

23 CHRISTOPHER CHIOU
24 Acting United States Attorney
District of Nevada


25 GUSTAV W. FYLER
26 Director
Consumer Protection Branch
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28 BLAIN R. JONES
Individually and on behalf of
AFFINITYLIFESTYLES.COM, INC.
and REAL WATER, INC.

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30 BRIANNA GARDNER
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34 J. LEE GRAY
35 Holland & Hart LLP
36 Attorney for Defendants.

5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

28. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this _____ day of _____, 2021.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

For Plaintiff

BRENT A. JONES
Individually and on behalf of
AFFINITYLIFESTYLES.COM, INC.
and REAL WATER, INC.

CHRISTOPHER CHIOU
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GUSTAV W. EYLER
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